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To: Distribution *W. McCoy, I. Skinner, W. Ryan.*
From: W. McCoy, I. Skinner, W. Ryan, Jr.

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Subject: Massachusetts Compliance.
 CDC Protocol For Nicotine, Quality Control Pools: Activity 7A14

Quality Control Pool

Section II.C. of the CDC protocol requires that:

*"At least two quality control pools prepared in the tobacco product matrix are recommended to be included in each analytical run. The tobacco product should be enriched with nicotine at the high and low ends of expected values for the tobacco product. The pools must be analyzed in duplicate in every run."*¹

It is not apparent how a tobacco product could be enriched with nicotine to generate these two quality control pools. There is no obvious way in which nicotine could be applied to a tobacco substrate to produce a material in which the nicotine is distributed as uniformly as it is in the original substrate. Therefore, in order to meet this requirement, the three tobaccos listed in Table 1 were obtained from the Tobacco Quality Audit Facility (TQAF) and ground to approximately 4 mm in size using a Robot Coupe Model RSI 6V Scientific Batch Processor. Evaluations of the Robot Coupe for sample preparation have been reported previously.²

Table 1. Candidate Tobaccos for Quality Pool

<u>Sample Code</u>	<u>Description</u>
N7BA-1	Domestic Flue Cured T970029
N7BA-2	Domestic Burley Tobacco T970024
N7BA-3	Oriental T970042

These three samples were then analyzed for alkaloids (ALK), nicotine (GC-Nic) and oven volatiles (OVA) by standard Philip Morris methods³. Table 2 lists the results both on an "As-Is" basis in which no adjustment has been made for the volatiles level of the samples and on a "Dry Weight Basis" (DWB) where the result are adjusted for the volatiles as measured by the oven volatiles test. Based on these results, tobaccos N7BA-1 and N7BA-3 were selected as high and low quality control pools, respectively.

Table 2 Analytical Results for Candidate Tobaccos

<u>Analysis</u>	<u>Tobacco Samples</u>		
	<u>N7BA-1</u>	<u>N7BA-2</u>	<u>N7BA-3</u>
Alkaloids (As-Is)	2.87	1.95	0.57
Alkaloids (DWB)	3.21	2.18	0.65
Nicotine (As-Is)	2.88	1.87	0.56
Nicotine (DWB)	3.23	2.09	0.63
Oven Volatiles	10.58	10.62	11.75

The two quality control pool tobaccos were subsequently analyzed for nicotine by the by the CDC protocol. The results are reported in Table 3.

Table 3: CDC Nicotine Data for Quality Control Pool Tobaccos

<u>Sample Code</u>	<u>Wt % Nicotine</u>							
	<u>Recovery Factor*</u>		<u>Not Corrected for Recovery</u>		<u>Corrected for Recovery*</u>		<u>Individual</u>	<u>Average</u>
			<u>Individual</u>	<u>Average</u>	<u>Individual</u>	<u>Average</u>		
N7BA-1-A	0.912	0.909	2.92	2.91	3.21	3.20		
	0.907		2.90		3.20			
	0.907		2.91		3.20			
N7BA-3-A	0.922	0.922	0.56	0.56	0.60	0.61		
	0.922		0.56		0.60			
	0.922		0.57		0.62			

The two quality control pool tobaccos were run in duplicate with each of the analytical runs made following the CDC protocol. The results, **not corrected for recovery**, are shown in Table 4. The data was not corrected for recovery because of concerns about this recovery correction.

**Table 4. Quality Control Pool Tobaccos
Analytical Runs**

<u>Tobacco</u>	<u>Run</u>	<u>Rep 1</u>	<u>Rep 2</u>	<u>Avg</u>	<u>S.D.</u>	<u>Range</u>
N7BA-1	1	2.83	2.85	2.84	0.02	0.03
	2	2.84	2.81	2.82	0.02	0.03
	3	2.86	2.85	2.85	0.01	0.01
	4	2.82	2.84	2.83	0.01	0.02
	5	2.84	2.87	2.86	0.02	0.03
N7BA-3	1	0.53	0.51	0.52	0.01	0.02
	2	0.53	0.52	0.53	0.01	0.01
	3	0.53	0.52	0.52	0.01	0.01
	4	0.54	0.52	0.53	0.01	0.01
	5	0.55	0.54	0.54	0.01	0.01

References:

1. Federal Register, Vol. 62, No. 85, p24115-24119, May 2, 1997.
2. J. Walton Wilkinson, "Evaluation of Robot Coupe® Model RSI 6V Scientific Batch Processor, Activity Code 8A18," memo to William Ryan, September 9, 1997.
3. W. S. Ryan, Jr., Editor, ARD Methods Manual.
4. W. McCoy, PM Notebooks 9345 and 9472.
5. I. Skinner, PM Notebook 9461.

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* The specified CDC protocol cited in the Federal Register/Vol.62. No.85, 24115 through 24119, Standards Addition Assay, II.B.1. through 12., was followed as written and results reported with specified recovery correction, II.D.8. In II.B.2., instructions and calculations related to the nicotine and internal standard concentrations are in error.